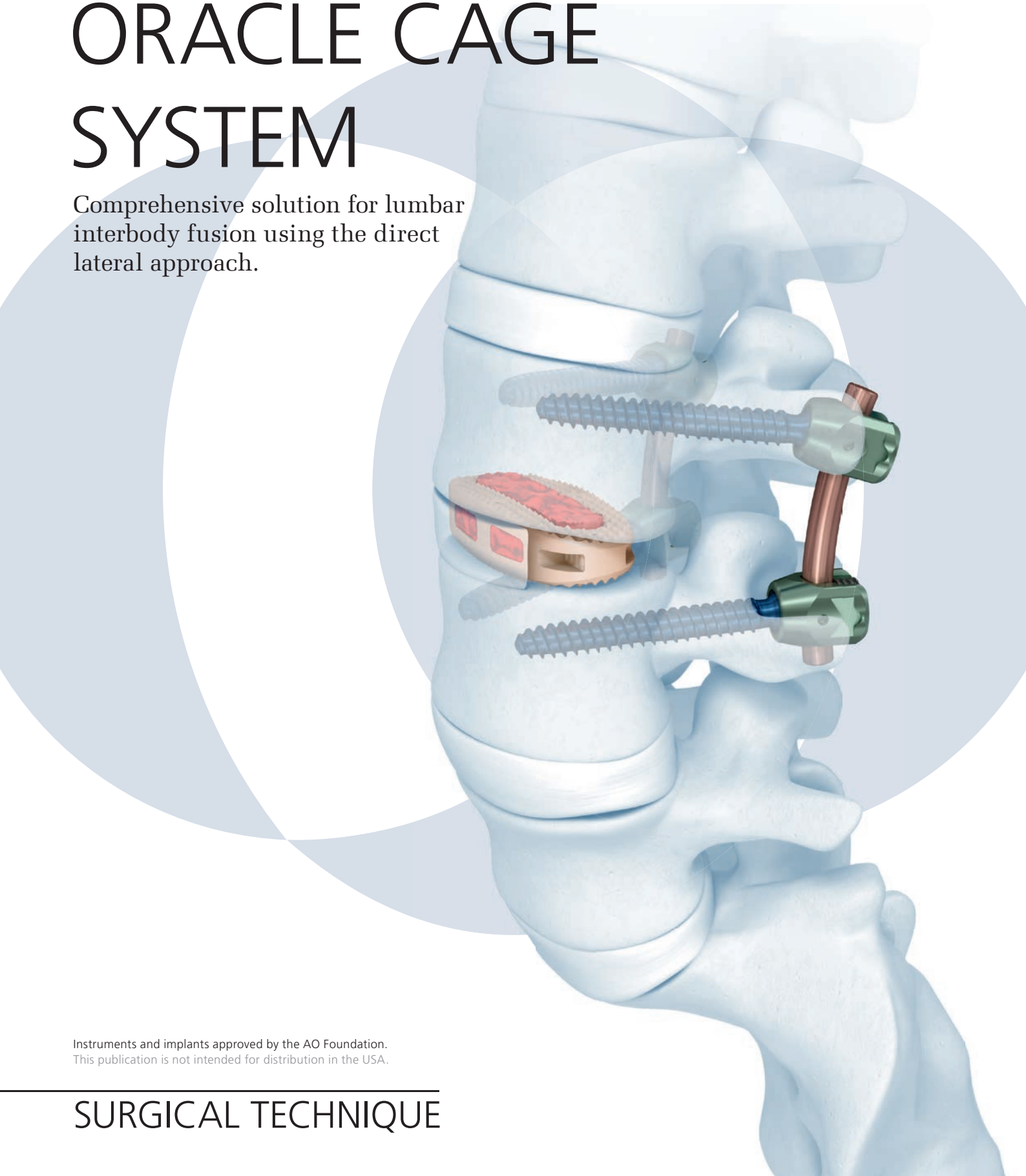
DePuy Synthes
COMPANIES OF Johnson & Johnson

ORACLE CAGE SYSTEM

Comprehensive solution for lumbar interbody fusion using the direct lateral approach.



Instruments and implants approved by the AO Foundation.
This publication is not intended for distribution in the USA.

SURGICAL TECHNIQUE

Image intensifier control

Warning
This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

TABLE OF CONTENTS

ORACLE CAGE SYSTEM

APPROACH

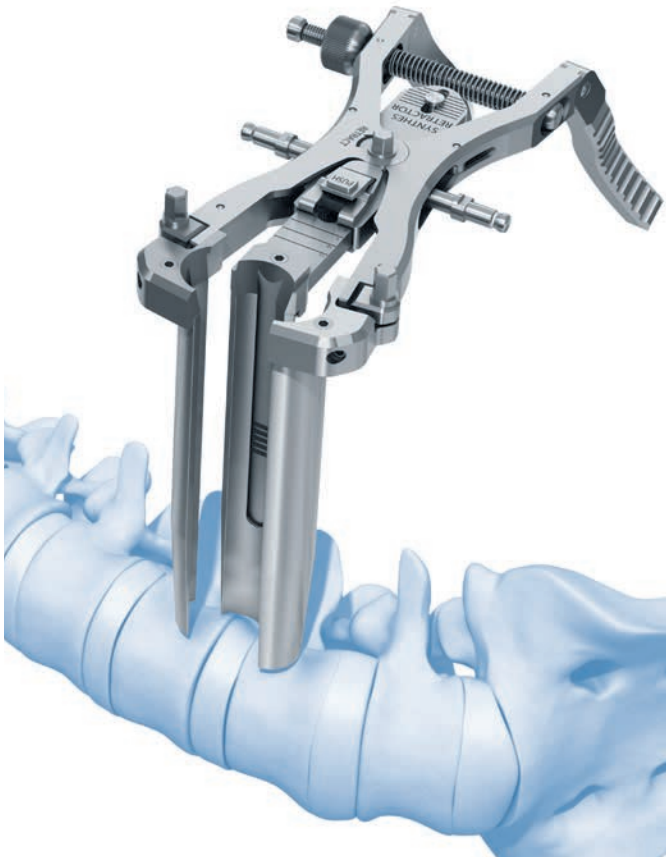
The Oracle Cage system is a modular and comprehensive set of implants and instruments designed to support a direct lateral approach to the lumbar spine. The direct lateral approach is a minimally invasive approach that avoids direct exposure of the anterior vessels, and posterior nervous and bony structures.

ACCESS

Oracle access instruments

Retractor
- Provides direct minimally invasive access to operative level
- Blades expand distally for additional access

Retractor accessories
- Light clip illuminates the surgical field
- Intradiscal anchor and retractor pins increase retractor stability
- Blade extensions provide an additional 10 mm to the blade length in-situ



DISCECTOMY

Oracle discectomy instruments

- Two styles of shavers, four-fluted and two-fluted, ream out disc material
- Bayoneted curettes ensure visibility while supporting a minimal exposure
- Instruments' matte finish reduces glare from OR lighting

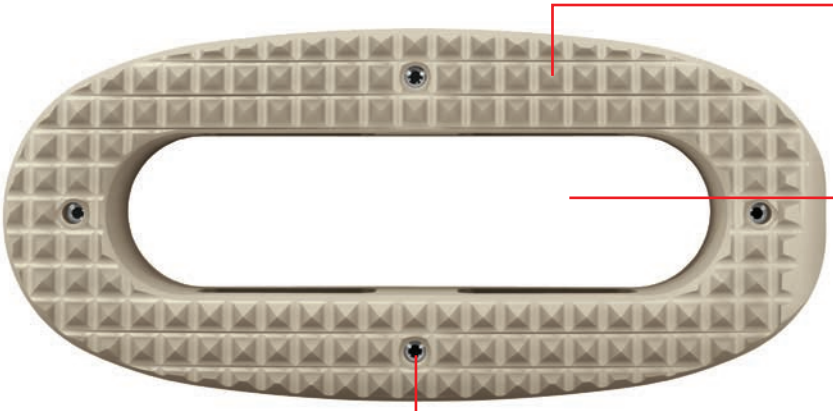
INSERTION

Oracle cage insertion instruments

- Trial implants' self-distracting nose allows for ease of insertion
- Slide hammer provides force required for trial implant removal
- Lateral Quick Inserter Distractor inserts and distracts in one simple step, without impaction

FEATURES AND BENEFITS

Oracle Cage is designed to meet the specific demands of lateral lumbar interbody fusion procedures. The implant is available in 4 medial/lateral lengths, 5 heights, and 2 sagittal profiles to accommodate various patient anatomies.



Pyramidal teeth
Provide resistance to implant migration

Large central canal
Accommodates autogenous bone graft or bone graft substitute to allow fusion to occur through the cage

Four radiographic marker pins
Enable visualization of implant position

The medial/lateral marker pins are located approximately 4 mm from the edges of the implant. The anterior/posterior marker pins are located approximately 2 mm from the edges of the implant.

Anatomic shape
Mimics the anatomy of the disc space

Self-distracting nose
Allows for ease of insertion

MATERIAL

Oracle Cage is manufactured from a biocompatible polymer[1] material embedded with four radiopaque marker pins, which allow the surgeon to radiographically determine the exact position of the implant, both intraoperatively and postoperatively.
The modulus of elasticity of the polymer is approximately between cancellous and cortical bone, which enables adequate compression of autograft in and around the implant, to aid in stress distribution and load sharing.

[1] Polyetheretherketone (PEEK)

AO PRINCIPLES

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.[1] They are:

- Anatomical reduction
- Stable internal fixation
- Preservation of blood supply
- Early, active pain-free mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements.[2]

AO Principles as applied to the spine[3]

Anatomic alignment
In the spine, this means reestablishing and maintaining the natural curvature and the protective function of the spine. By regaining this natural anatomy, the biomechanics of the spine can be improved, and a reduction of pain can be experienced.

Stable internal fixation
In the spine, the goal of internal fixation is to maintain not only the integrity of a mobile segment, but also to maintain the balance and the physiologic three-dimensional form of the spine.[4] A stable spinal segment allows bony fusion at the junction of the lamina and pedicle.

Preservation of blood supply
The proper atraumatic technique enables minimal retraction or disturbance of the nerve roots and dura, and maintains the stability of the facet joints. The ideal surgical technique and implant design minimize damage to anatomical structures, i.e. facet capsules and soft tissue attachments remain intact, and create a physiological environment that facilitates healing.

Early, active mobilization
The ability to restore normal spinal anatomy may permit the immediate reduction of pain, resulting in a more active, functional patient. The reduction in pain and improved function can result when a stable spine is achieved.

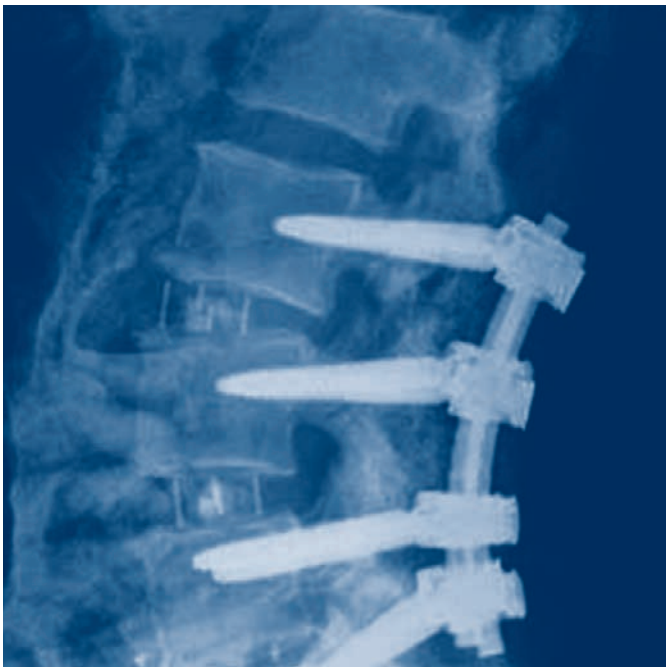
1 M.E. Müller, M. Allgöwer, R. Schneider, and H. Willenegger: AO Manual of Internal Fixation, 3rd Edition. Berlin; Springer-Verlag 1991
2 Ibid.
3 Aebi M, Arlet V, Webb JK (2007). AOSpine Manual (2 vols.), Stuttgart, New York: Thieme
4 Ibid.

INDICATIONS AND CONTRAINDICATIONS

Intended Use
The Oracle Cage is intended to replace lumbar intervertebral discs and to fuse the adjacent vertebral bodies together at vertebral levels L1 to L5. Additionally, the use of autogenous bone or bone graft substitute as well as supplemental fixation is always recommended. Oracle implants are inserted via the lateral approach.

Indications
Lumbar pathologies with indicated segmental spondylodesis, e.g.:
- Degenerative disc diseases and spinal instabilities
- Revision procedures for post-discectomy syndrome
- Pseudoarthrosis or failed spondylodesis
- Degenerative spondylolisthesis
- Isthmic spondylolisthesis

Oracle Cage is intended to be used in combination with supplemental fixation.



Two-level lateral view of Oracle and Pangea immediately postoperative.

Contraindications
- Vertebral body fractures
- Spinal tumors
- Major spinal instabilities
- Primary spinal deformities

1
Preoperative Planning and Preparation

Sets

187.310	SynFrame Basic System in Vario Case*
01.609.102 or 01.809.002 and 01.809.018 or 01.612.100 or 01.809.040	Set SynFrame RL, lumbar** Oracle Access Instrument Set Stability System Set Set for MIS Support System INSIGHT Lateral Access System Set
01.809.003	Oracle Discectomy Instrument Set
01.809.004	Oracle Cage Insertion Instrument Set

Optional

03.662.027S	Neuromonitoring Stimulation Probe
03.662.028S	Electrode Kit for Neuromonitoring
03.662.029	Handle for Neuromonitoring Stimulation Probe
03.809.943	Retractor Pin
03.809.925S	Light Clip for Oracle Retractor, sterile
01.809.011	Dilation Instrument Set
01.605.903	Set for Minimally Invasive Posterior Instuments

Have all necessary imaging studies readily available to plan implant placement and visualize individual patient anatomy.

Have all sets readily available prior to surgery.

* SynFrame Basic System contains instruments that allow for direct mounting to the operating table.
** SynFrame RL, lumbar contains radiolucent soft tissue retractors and semi-transparent bone levers.

2
Patient Positioning

Optional set

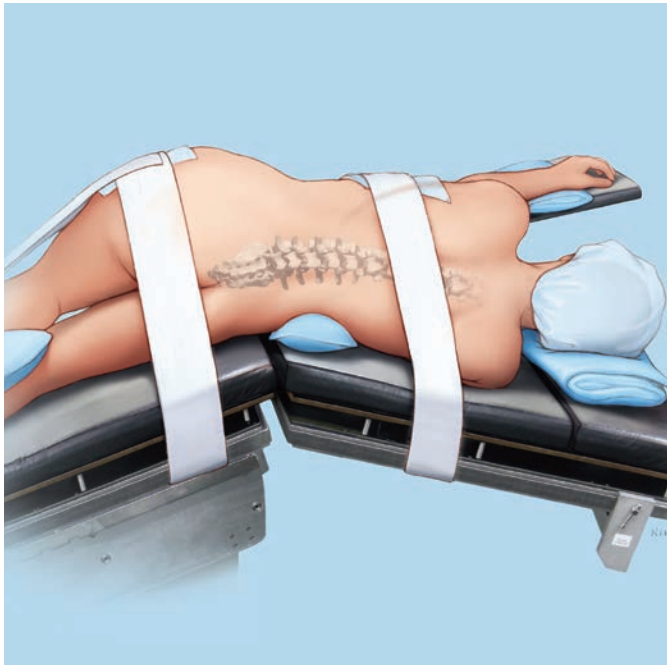
03.662.028S Electrode Kit for Neuromonitoring

Place the patient in a lateral decubitus position. A bolster placed underneath the hip, to aid in opening the space between the twelfth rib and iliac crest, is recommended. It is also recommended to flex the table, to aid in opening the space between the twelfth rib and iliac crest. Ensure that the rotational alignment is correct. Secure the patient to the table.

Precaution: **Prevent undue pressure points when positioning and securing the patient.**

Note: **If neuromonitoring is planned, the neurophysiologist or neuromonitoring technician should apply all appropriate electrodes prior to patient positioning.**

See respective neuromonitoring surgical technique for details of Neuromonitoring Kit usage.
Use the universal arm and table clamp to stabilize the retractor to the OR table. Turn the table clamp lever counterclockwise to loosen. Slide the table clamp onto the OR table rail.
Insert the post of the universal arm through the opening of the table clamp with the articulation of the arm facing the patient. Turn the table clamp lever clockwise to tighten.



3
Access and Exposure

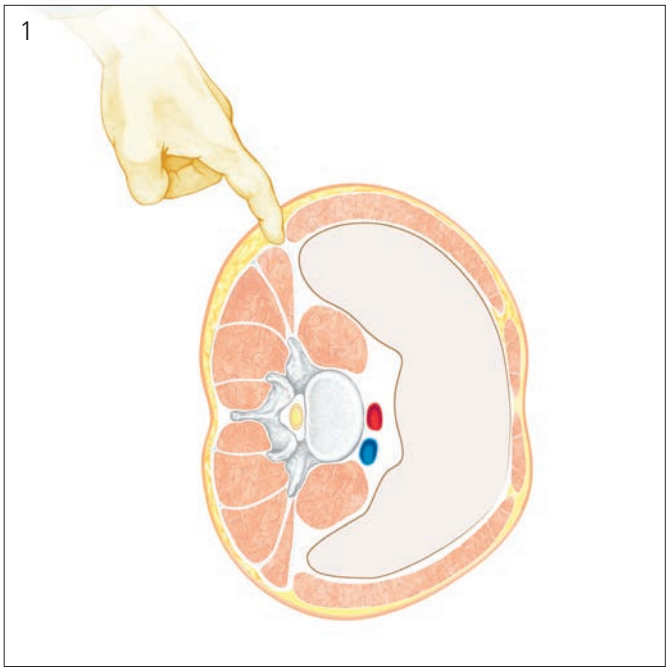
Locate the correct operative level and incision with fluoroscopic views. Make a skin incision targeting the anterior third of the intervertebral disc space.

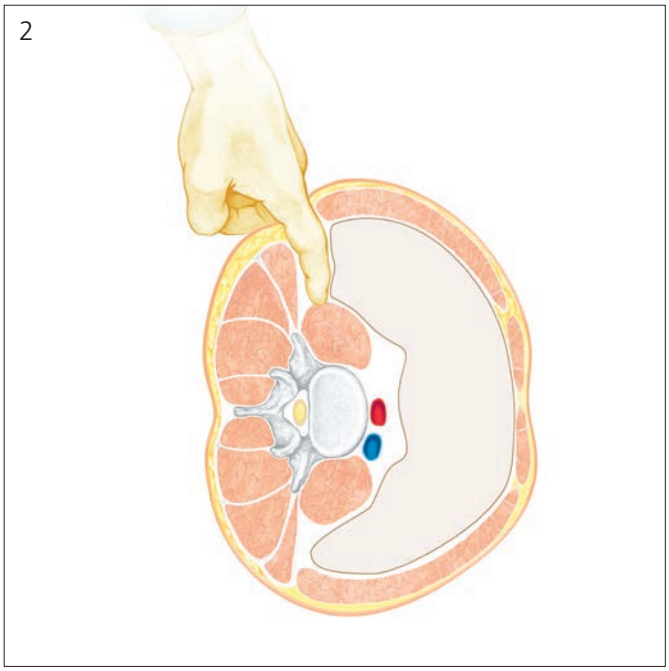
Note: **Use a longitudinal incision if multiple levels will be fused.**

A. Approach spine with tissue dissector

Instrument	
03.809.860	Tissue Dissector

Once the skin incision is made and the subcutaneous tissue is taken down, the oblique muscles of the abdomen should be visible. Separate the muscle fibers with blunt dissection and enter the retroperitoneal space (1). Move the peritoneum anterior with forefinger and continue blunt dissection to palpate down to the transverse process. Slide forward to psoas muscle (2).



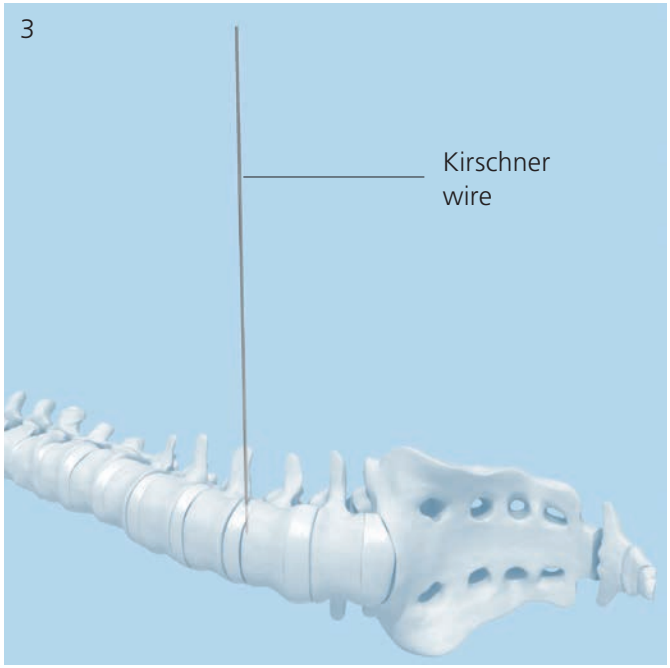


Map out a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended, to ensure targeting of the anterior two-thirds of the disc space of concern. The anterior third of the psoas muscle is the most likely safe zone for avoiding the neural elements of the lumbar plexus.[1]

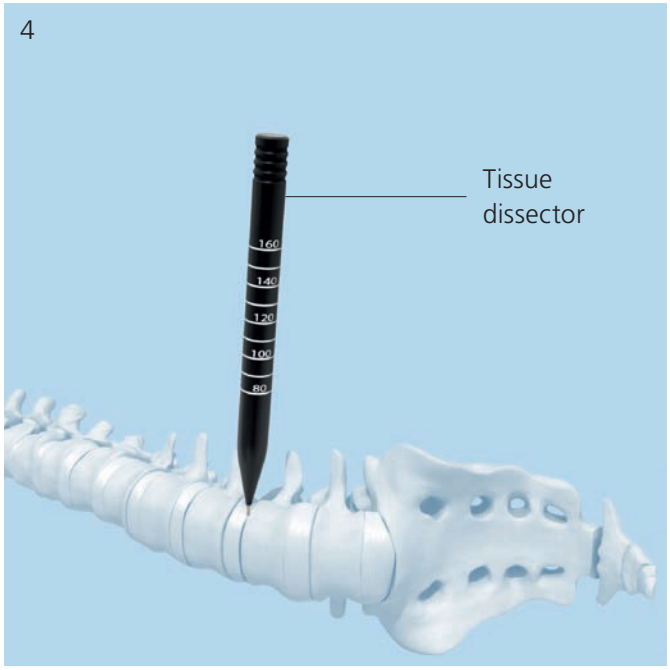
Push a Kirschner wire through the psoas muscle in the middle of the safe zone landing and into the annulus of the desired intervertebral disc space (3). Use fluoroscopy with lateral images to determine the location of the Kirschner wire.

Separate the psoas muscle using the tissue dissector and push the tissue dissector into the disc space (4). Use fluoroscopy to determine the location of the tissue dissector. Remove the Kirschner wire.

3



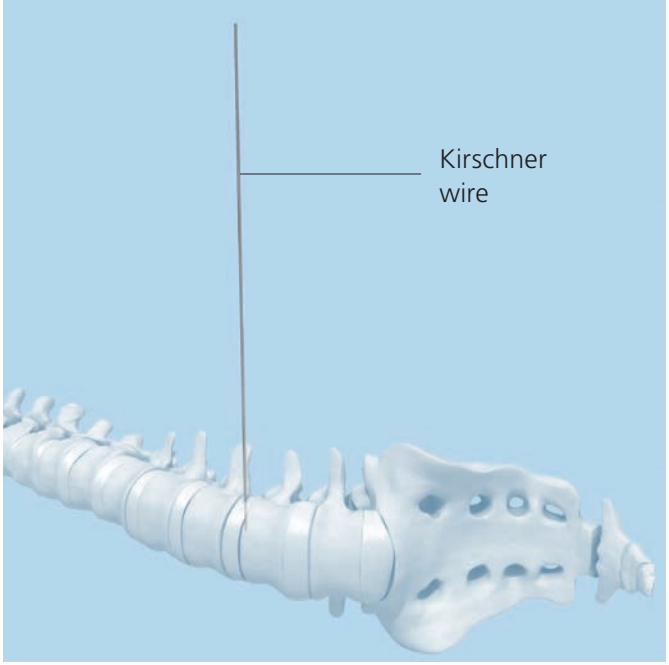
4



[1] Takatomo Moro, MD, Shin-ichi Kikuchi, MD, PhD, Shin-ichi Konno, MD, PhD and Hiroyuki Yaginuma, MD, PhD: "An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery.", Spine 2003; Volume 28, Number 5, pp 423-428.

B. Approach spine with dilators

Instruments	
03.809.851	Oracle Dilator, centred, small
03.809.853	Oracle Dilator, centred, medium
03.809.855	Oracle Dilator, centred, large
03.809.858	Oracle Dilator, not centred, small
03.809.859	Oracle Dilator, not centred, large
02.809.001	Kirschner Wire ∅ 1.6 mm with blunt tip, length 285 mm
02.809.002	Kirschner Wire ∅ 3.0 mm with blunt tip, length 285 mm



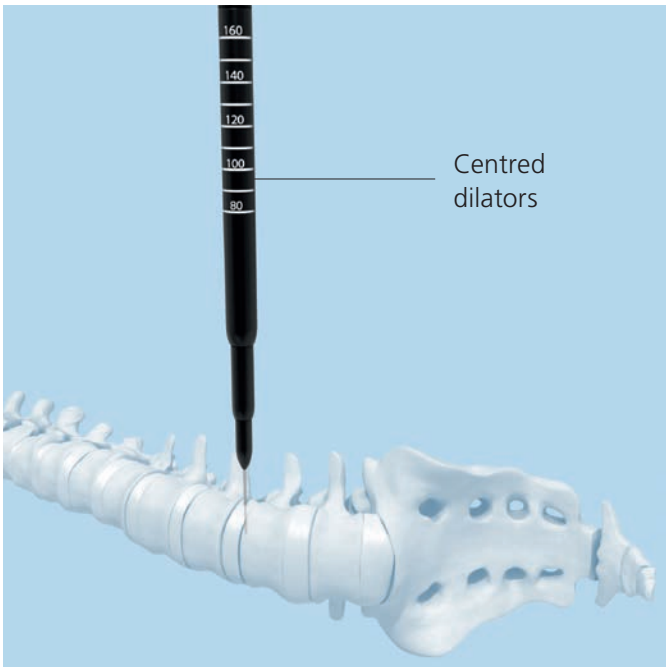
If sequential dilation is planned, map out a safe corridor through the psoas muscle to the lumbar spine. Fluoroscopy is recommended to ensure targeting of the anterior two-thirds of the disc space of concern. The anterior third of the psoas muscle is the most probable safe zone for avoiding the neural elements of the lumbar plexus.[2]

Push a Kirschner wire through the psoas muscle in the middle of the safe zone landing and into the annulus of the desired intervertebral disc space. Use fluoroscopy with lateral images to determine the location of the Kirschner wire.

[2] Ibid pp 423-428.

Separate the psoas muscle by inserting the smallest diameter dilator over the Kirschner wire. Repeat with the next larger diameter dilator until the required dilation is achieved. Use fluoroscopy to determine the location of dilator.

Alternative: **Not centred Oracle Dilators (03.809.858 and 03.809.859) are also available for sequential dilation, and should always be used with a 3.0 mm Kirschner wire.**



C. Approach spine with neuromonitoring and tissue dissector or dilators

Instrument	
03.662.027S	Neuromonitoring Stimulation Probe
03.662.029	Handle for Neuromonitoring Stimulation Probe

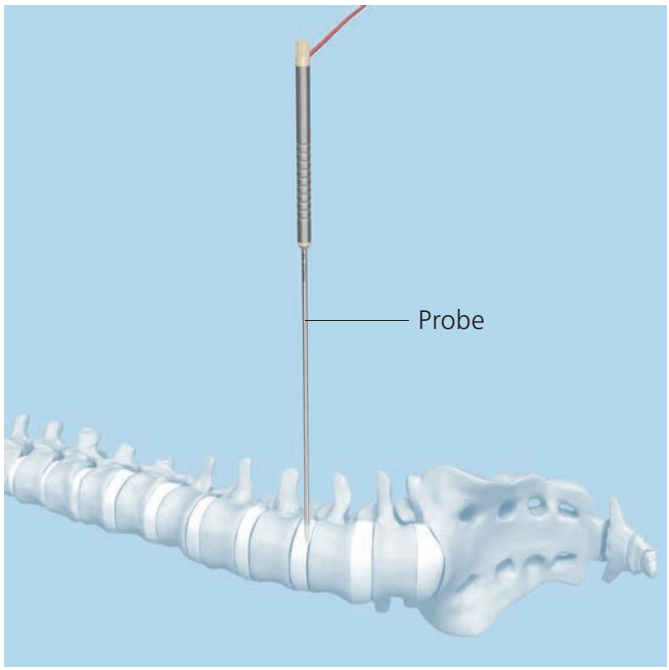
If neuromonitoring is planned, assemble the monopolar stimulating probe.

Attach the cable to the handle. Attach the handle and cable assembly to the proximal end of the monopolar stimulating probe. Pass the opposite end of the cable to the neurophysiologist or neuromonitoring technician.

Map out a safe corridor through the psoas muscle to the lumbar spine by stimulating with the monopolar probe.

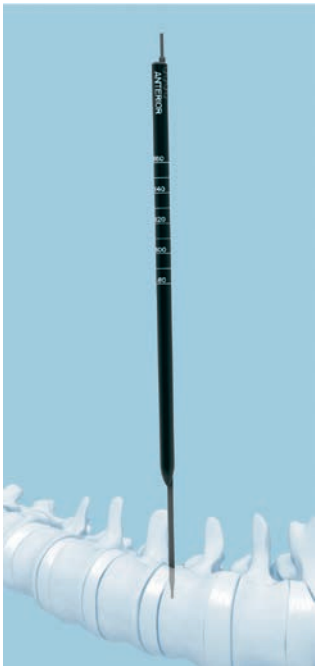
Push the stimulating probe through the psoas muscle in the middle of the safe zone landing and into the annulus of the desired intervertebral disc space. Use fluoroscopy with lateral images to determine the location of the stimulating probe.

See respective Neuromonitoring surgical technique for details of Neuromonitoring Kit usage.



Remove the handle from the monopolar stimulating probe and perform sequential dilation with the not centred Oracle Dilators (03.809.858 and 03.809.859) over the stimulating probe.

Use fluoroscopy to determine location of the dilators and rotate accordingly to adjust access window. Subsequently probe around the dilators with a second probe to ensure avoidance of nerve structures.



4
Soft Tissue Retraction

A. Retraction with SynFrame

Sets	
187.310	SynFrame Basic System in Vario Case
01.609.102	Set SynFrame RL, lumbar

It is recommended to use at least three radiolucent SynFrame retractors to hold the soft tissue and enable the passage of the instrumentation. Because there might be significant forces that are applied by the psoas, the retractors need to be well stabilized with the aid of the retractor holders and the SynFrame ring.

For further information please refer to SynFrame Handling Technique (036.000.065).

Note: **Careful positioning of the retractors is required to avoid soft tissue damage.**

B. INSIGHT Lateral Access System

Sets	
01.809.040	INSIGHT Lateral Access System Set, complete

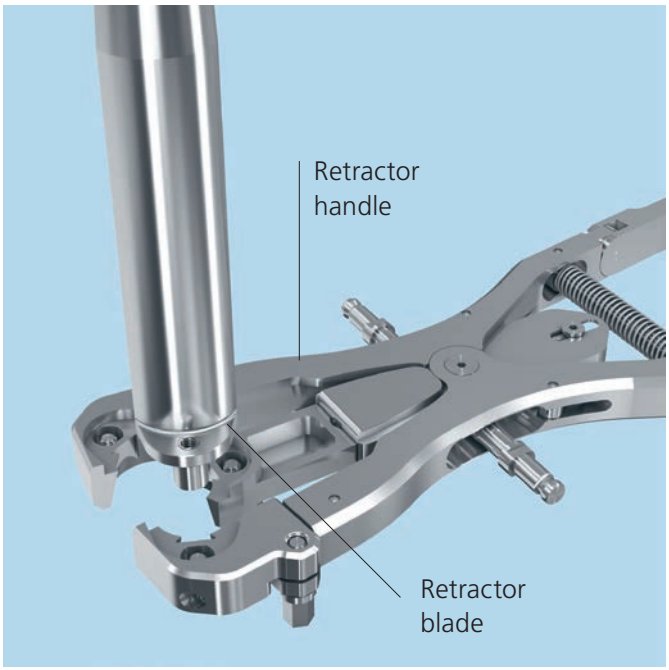
For details of operating and use, please refer INSIGHT Lateral Access System surgical technique.

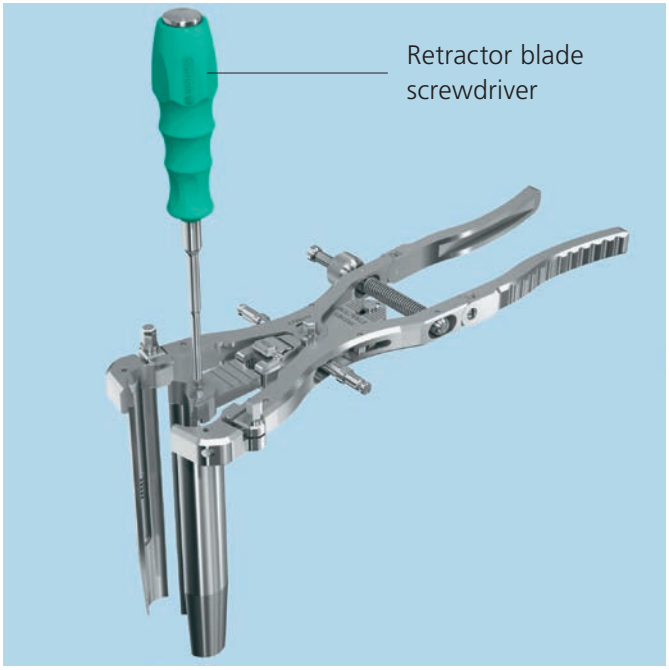
C. Retraction with Oracle access instruments

Instruments	
03.809.857	Retractor Blade Screwdriver
03.809.900	Oracle Retractor Handle
03.809.903– 03.809.915	Oracle Retractor Blades, 40 mm–160 mm
03.809.923	Retractor Extension Driver
03.809.941	Universal Arm
03.809.942	Table Clamp for Universal Arm
388.140	Socket Wrench 6.0 mm, with straight handle
Optional instruments	
03.612.031	Fibre Optic Cable for Light Strip
03.809.925S	Light Clip for Oracle Retractor, sterile
03.809.943	Retractor Pin
03.820.101	Screwdriver
03.809.918	Oracle Retractor Blade Extension
03.809.919	Oracle Retractor Intradiscal Anchor

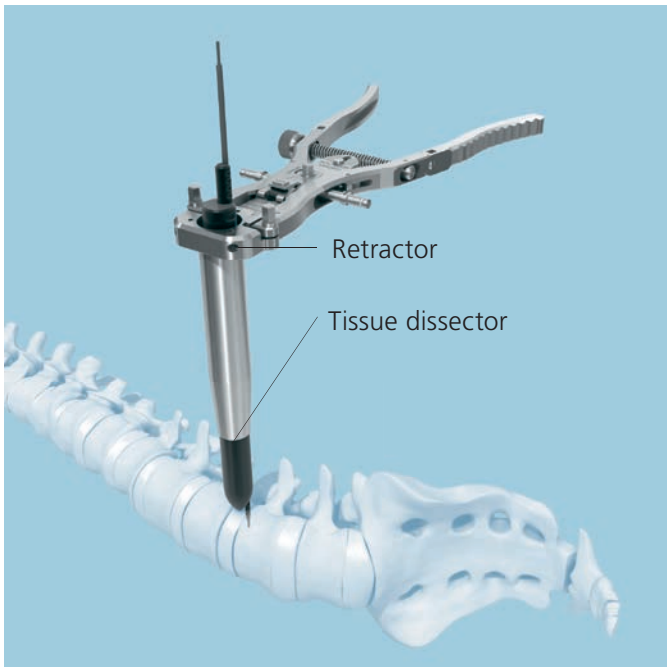
Determine the appropriate retractor blade lengths from the depth indicators on the tissue dissector or optional dilators. Assemble the blades to the retractor handle with the retractor blade screwdriver.

Important: **Do not over-torque the screwdriver. Two-finger tightening is sufficient to retain the blades to the retractor handle.**





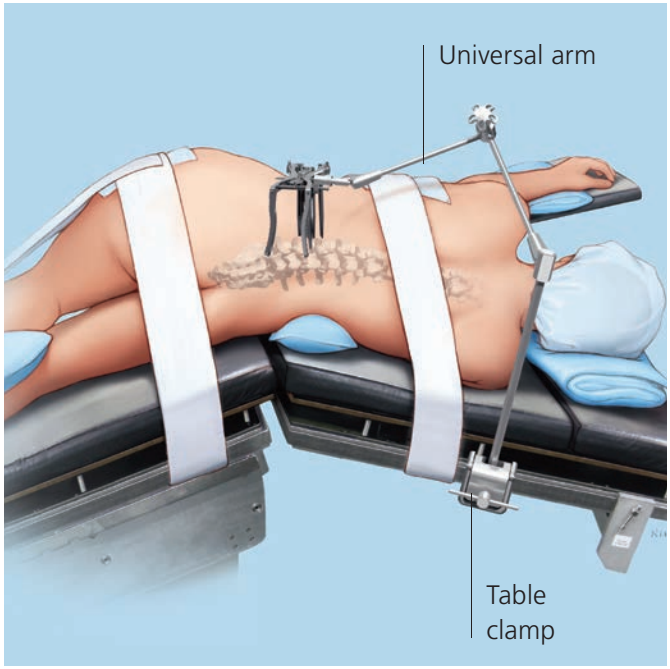
Slide the retractor over the tissue dissector or optional dilator. Use an anterior/posterior fluoroscopic image to determine the position of the retractor blade tips. Retractor blades should contact the disc space and/or vertebral endplates, perpendicular to the disc space. If they do not contact the disc space and/or vertebral endplates, push down on the retractor to push through the psoas muscle before opening the retractor, to minimize tissue creep.



Insert the universal arm into the connector of the retractor handle and turn the knob on the arm clockwise to tighten.

The MIS Support System may also be used to stabilize the retractor (refer to the MIS Support System Assembly Guide).

Remove the tissue dissector or optional dilator, open retractor to the desired position, and turn the speed nut to lock it.

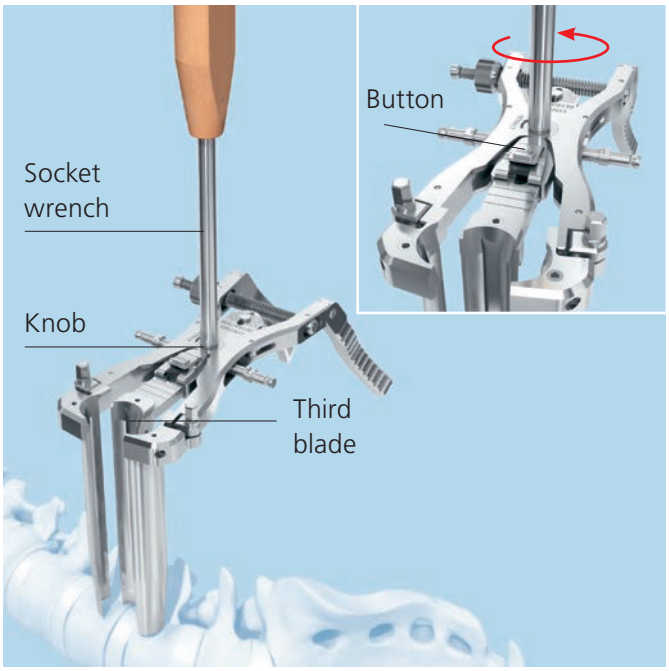


Retract the third blade posteriorly by turning the knob clockwise with the socket wrench. The third blade should not be placed much beyond the posterior ⅓ margin of the disc space to avoid any neural structures. To release the amount of retraction, push the button and turn the knob counterclockwise with the socket wrench.

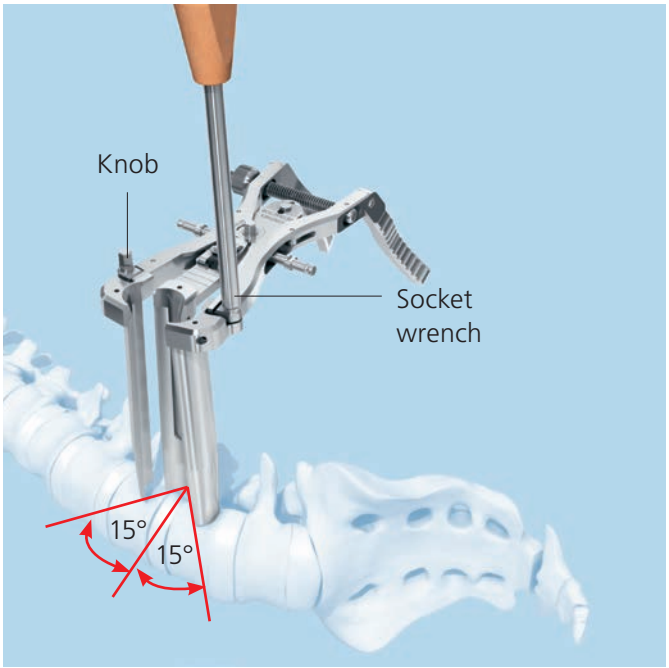
With the blades open and secure, slide the light clip down the grooves of the cranial or caudal blades of the retractor. Insert the light clip to increase visualization. Insert the light clip into the end of the fiber optic light cable. Turn on the light source.

Note: If the neuromonitoring kit is used, stimulate the exposed area with the monopolar stimulating probe to ensure that the surgical field is free of nerve structures.

Precaution: Do not stimulate against the retractor.



For further retraction, the cranial and caudal blades can independently provide up to 15° of cranial and caudal angulation. Use the socket wrench on either the cranial or caudal knob. Turn counterclockwise to release, or clockwise to tighten into the desired position.

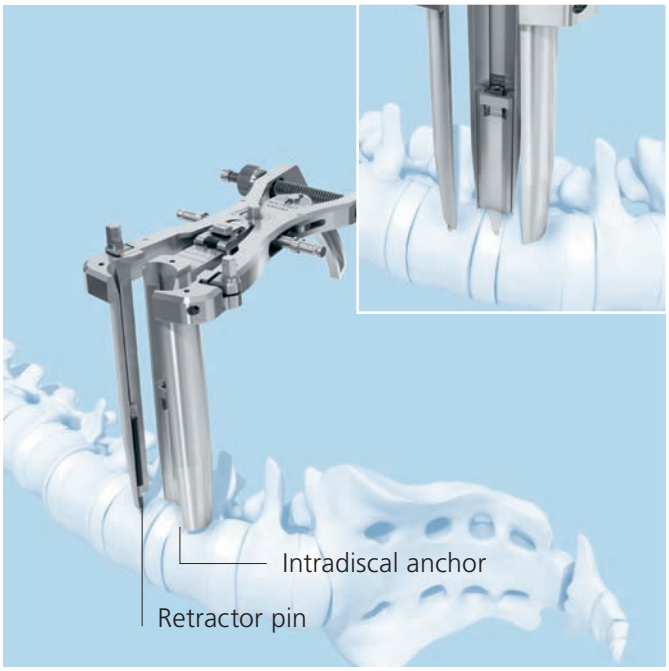


For increased retractor stability, attach the intradiscal anchor to the third blade by screwing the anchor onto the retractor extension driver (03.809.923). Slide the anchor down the grooves of the third blade. Unscrew the driver from the anchor.

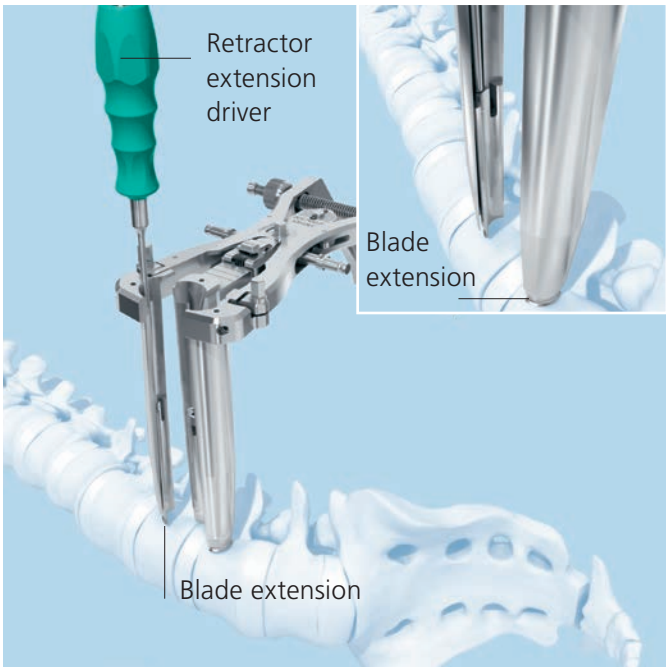
For additional retractor stability, attach the retractor pin to the screwdriver (03.820.101). Slide the pin down the grooves of either the cranial or caudal blade and screw the pin into the vertebral body.

Tip: **Remove the retractor pin before any distraction or trialing of disc space.**

Precaution: **Prior to intradiscal anchor and/or retractor pin placement, both lateral and anterior-posterior fluoreoscopy should be performed to confirm that the retractor is safely placed for such instrument insertion.**



If the psoas or soft tissue creeps beneath the cranial or caudal blades, the blade extensions provide an additional 10 mm extension. Assemble the blade extension to the Retractor extension driver (03.809.923) and slide the blade extension down the grooves of either the cranial or caudal blade, while holding back the psoas muscle.



5
Discectomy

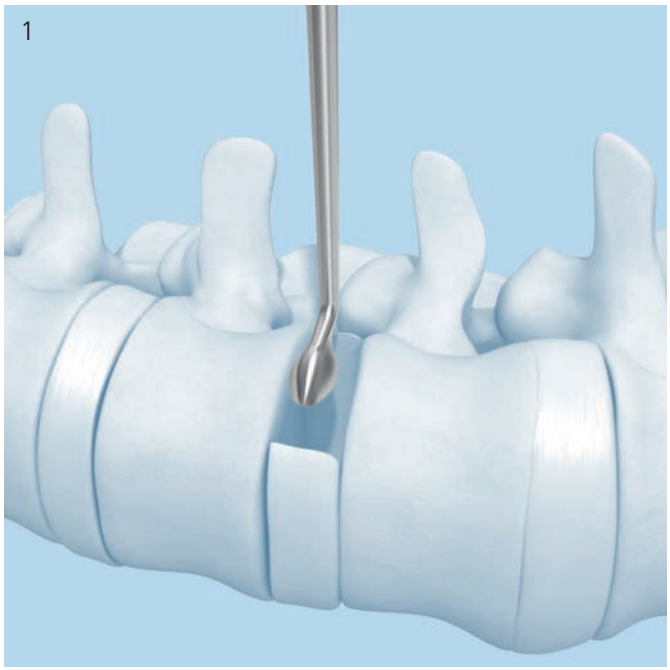
Instruments	
03.605.001/ 03.605.002	Rongeur for Intervertebral Discs, straight, widths 4 and 6 mm, length 330 mm
03.605.004	Periosteal Elevator, width 20 mm
03.809.819– 03.809.827	Oracle Shavers, paddle-shaped 9 mm–17 mm heights
03.809.829– 03.809.837	Oracle Shavers, 9 mm–17 mm heights
03.809.861– 03.809.870	Oracle Curettes, bayoneted, straight, up biting or forward biting, width 5.5 or 7.5 mm
03.809.872– 03.809.873	Oracle Ring Curettes, bayoneted, width of tip 8 mm and 6 mm
394.951	T-Handle with Quick Coupling

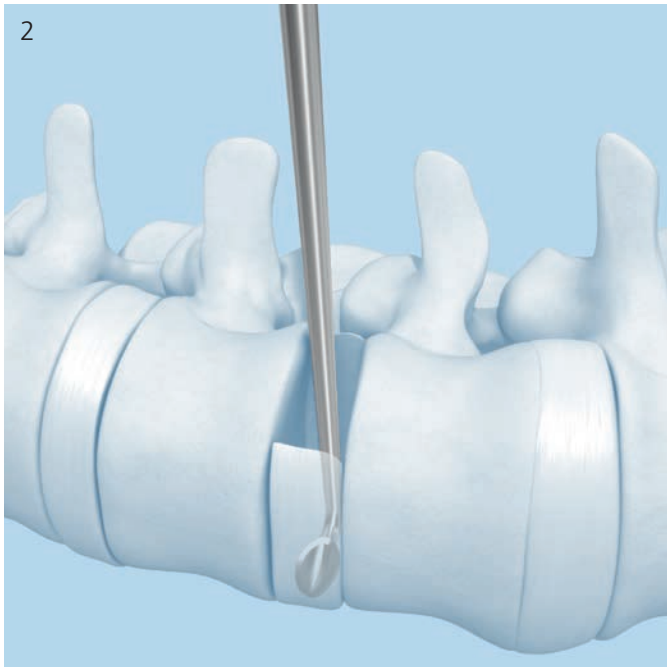
Optional Instruments	
03.809.875– 03.809.877	Oracle Spreaders, heights 9 mm–13 mm

Remove disc material from the intervertebral space using any of the following: periosteal elevator, cup and ring curettes, rongeurs or shavers.

The periosteal elevator can be used to loosen the disc material from the endplates. Use fluoroscopy to ensure complete removal of disc material and safe instrument placement.

Use the forward biting cup curettes to push disc material (1) and the 90° up-biting curettes to collect disc material from the disc space (2). The cup curettes are available in two cup sizes, 5.5 mm denoted by the white band, and 7.5 mm denoted by the green band.

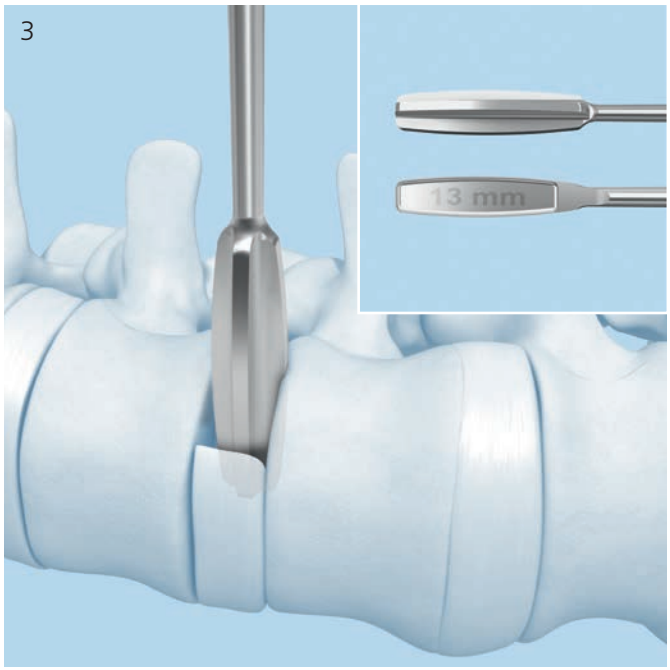




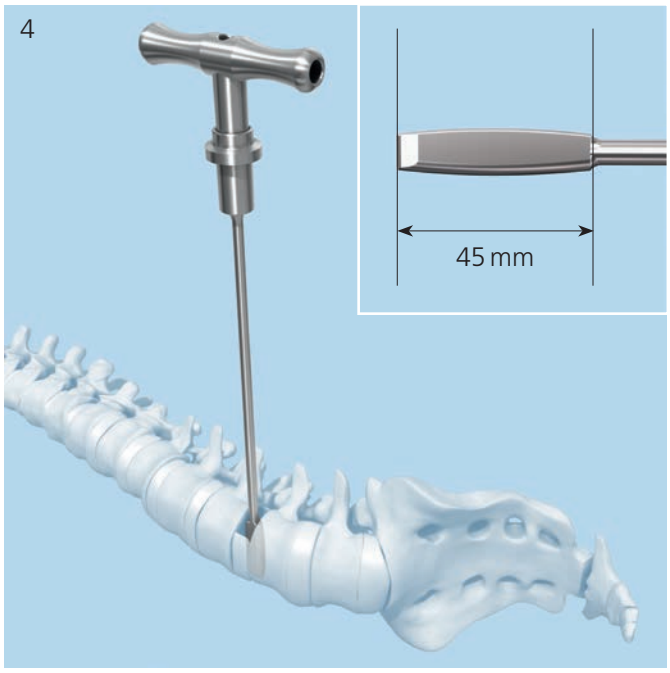
The shavers can be used initially to ream out disc material or for final removal of the disc material and cartilaginous tissue (3).

Note: **The medial/lateral dimension of the shavers is 48 mm (3: inset). The height is undersized by 1 mm compared to the implant height to ensure a tight fit for final implant insertion.**

After the discectomy is performed, break through the contralateral part of the annulus with the periosteal elevator. Use a fluroscopic image to determine that the contralateral annulus has been perforated.



If the disc is severely collapsed, use the spreaders to distract and recreate the normal disc height, restore lordosis and open the neuroforamen (4).



Note: **The medial/lateral dimension of the spreaders is 45 mm (4: inset).**

Tip: **In order to prevent any risk of damaging vital structures, it is recommended to keep intact a few millimeters of the annulus on both anterior and posterior sides. The anterior and the posterior longitudinal ligaments (ALL and PLL) must stay intact in all cases.**

Precaution

- **In order to prevent weakening of bony structures, any damage to the vertebral endplates caused by curettes, shavers and/or spreaders must be avoided.**
- **Do not damage major vascular structures, nerve roots, the lumbar plexus and/or the spinal cord.**
- **The anterior and posterior longitudinal ligaments (ALL and PLL) must stay intact in all cases.**
- **Avoid overdistraction in order to prevent damage to the soft tissue structures.**
- **Turn the spreader clockwise by a quarter turn to distract the segment. Turn the spreader counterclockwise for removal. Turning the spreader in the wrong direction may cause damage to the bony structures.**

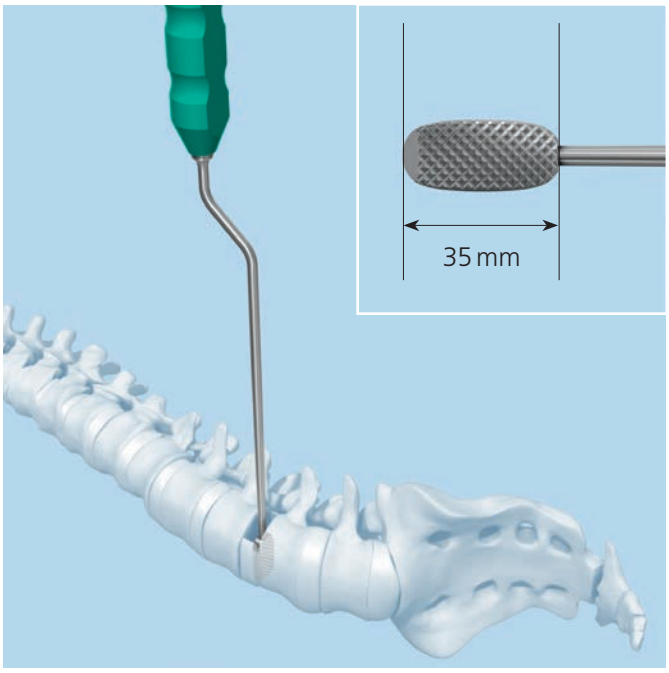
6
Prepare Endplates

Instrument	
03.809.849	Oracle Rasp

When the discectomy is complete, use the rasp to remove the superficial cartilaginous layers of the endplates and to expose the bleeding bone.

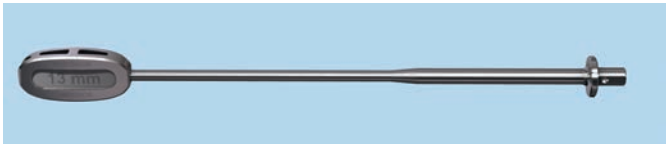
Important: **Excessive removal of the subchondral bone may weaken the vertebral endplate. The entire removal of the endplate may result in subsidence and a loss of segmental stability.**

Note: **The medial/lateral dimension of the rasp is 35 mm. The height is 8 mm.**

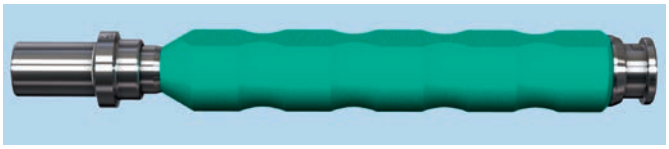


7a
Insert trial Implant

Instruments	
03.809.229– 03.809.237	Oracle Trial Implants, 0° angle, heights 9–17 mm
03.809.629– 03.809.237	Oracle Trial Implants, 8° angle, heights 9–17 mm
03.809.930	Handle with Quick Coupling

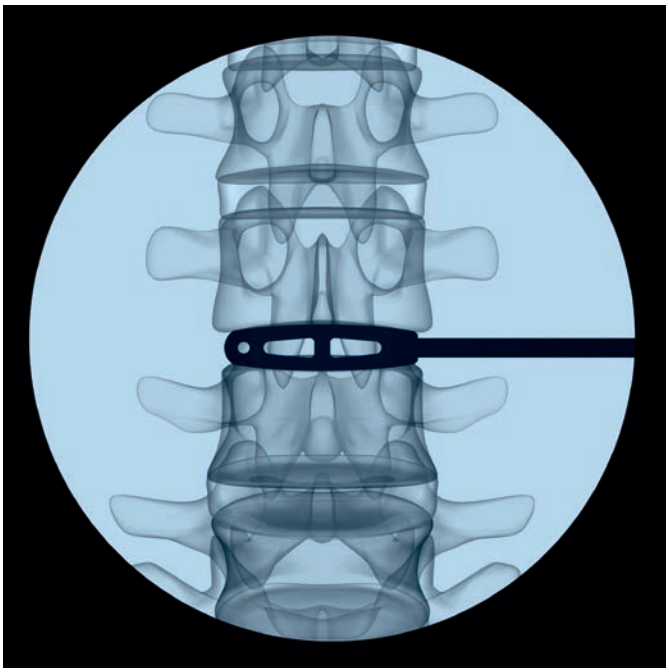


Oracle Trial Implant


Handle with Quick Coupling

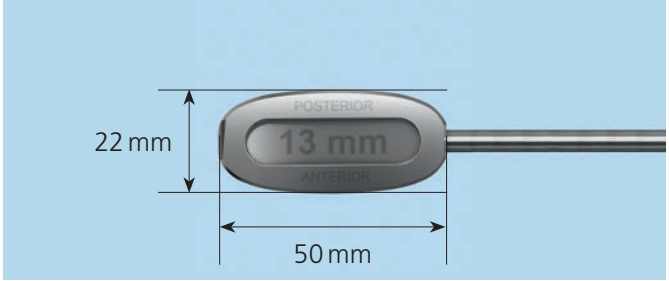
Connect an appropriately sized trial implant to the handle. Insert the trial implant into the disc space, ensuring that the orientation of the trial implant is correct. Each lordotic trial implant is etched with anterior and posterior markings. Controlled and light hammering on the trial implant handle may be required to advance the trial implant into the intervertebral disc space.

Use fluoroscopy to confirm the fit of the trial implant. Each trial implant has a center opening that can be visualized in an anterior/posterior fluoroscopic view. The bridge dividing the center opening should align with the spinous processes or be equidistant from the pedicles on an anterior/posterior fluoroscopic view. If the trial implant appears too small or too tight, try the next larger or smaller size height until the most secure fit is achieved.



Note: **The anterior/posterior dimension of the trial implants is 22 mm in order to correspond with the implant.**

The trial implants' medial/lateral dimension is 50 mm. Use fluoroscopy to determine the appropriate medial/lateral dimension of the implant for the patient. Take a lateral fluoroscopic image to determine the anterior and posterior position of the trial implant. The trial implant, and ultimately the implant, should sit within the anterior 2/3 of the intervertebral disc space. The height of the trial implants is undersized by 1 mm, compared to the implant, to ensure a tight fit for final implant insertion.

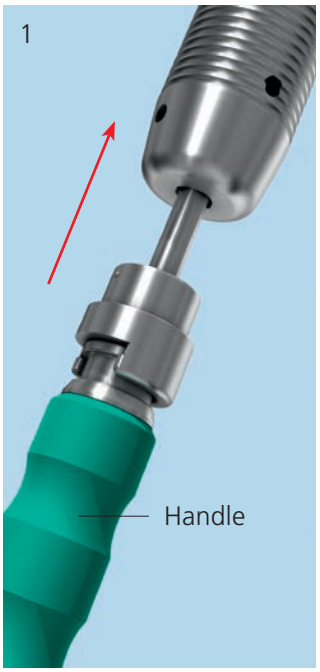


7b
Remove trial implant

Instrument	
03.809.972	Oracle Slide Hammer

Slide the Oracle slide hammer onto the end of the handle with quick coupling. While holding the handle with one hand, apply an upward force to the slide hammer with the other hand (1). Repeat this process until the trial implant is removed.

Remove the Oracle slide hammer from the handle by pushing on the end of the slide hammer (2).



8
Insert Implant

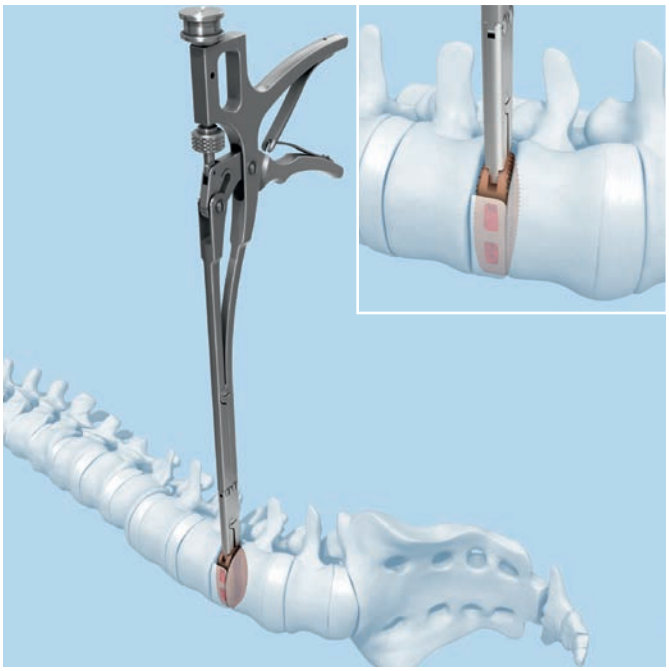
A. Insertion with implant holder

Instruments	
03.809.874	Implant Holder for Oracle Cage
03.809.881	Oracle Impactor

Select an Oracle implant that corresponds to the height measured using the trial implant in the previous steps.

Attach the jaws of the holder to the instrument slot of the implant and tighten the speednut. Ensure that the implant is held flush against the neck of the implant holder and securely in the jaws of the holder.

After being fixed to the implant holder, the interior of the implant can be packed with autogenous bone or bone graft substitute. Introduce the implant into the intervertebral disc space, ensuring that the orientation of the implant is correct.



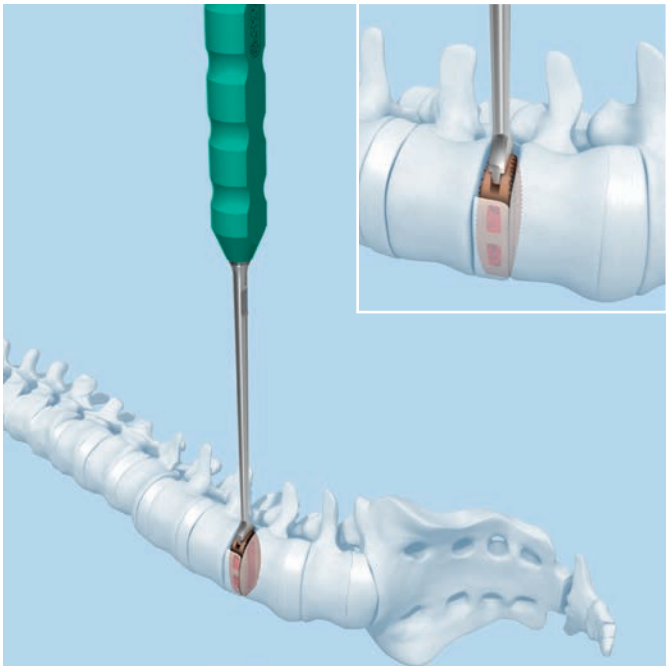
- Remove the implant holder and use the impactor to seat the implant in its final position.

- Use fluoroscopy to determine the position of the implant. On an anterior/posterior fluoroscopic image, the two anterior/posterior radiopaque pins of the implant should appear as one marker. The midline pins should line up with the midportion of the spinous process and the lateral pins should be equidistant from the lateral edges of the vertebral bodies.

  Note: **The medial/lateral marker pins of the implant are located approximately 4 mm from the edges of the implant.**

- With a medial/lateral fluoroscopic image, the medial/lateral radiopaque pins of the implant should appear as one marker. The most anterior, middle radiopaque marker should be countersunk from the anterior edge of the vertebral bodies.

  Note: **The anterior/posterior marker pins of the implant are located approximately 2 mm from the edges of the implant.**



B. Insertion with lateral quick inserter distractor

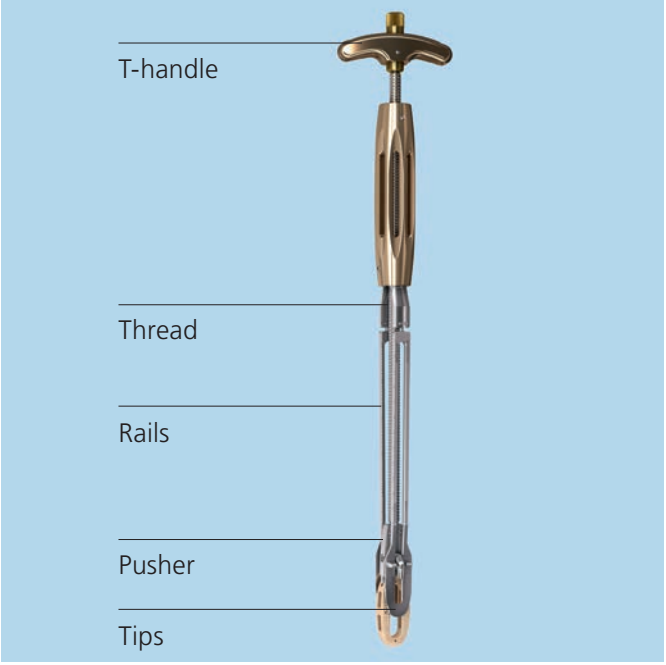
Optional instrument	
03.809.921	Oracle Lateral Quick Inserter Distractor (SQUID)

Select an Oracle implant that corresponds to the height measured using the trial implant in the previous steps.

If using the Oracle lateral quick inserter distractor, turn the T-handle counterclockwise until the pusher stops. When the thread is completely turned, place the instrument flat on the table to load the implant.

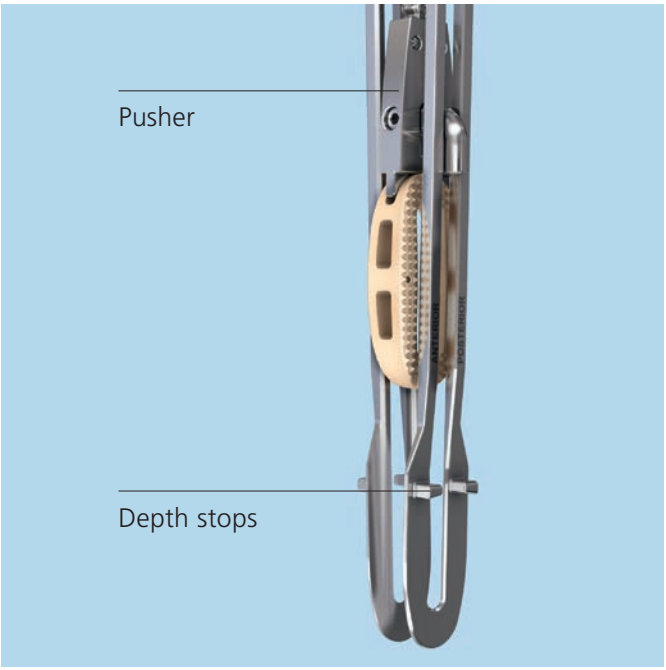
Pack the interior of the implant with autogenous bone or bone graft substitute. Place the implant into the rails, ensuring the implant is seated into the pusher.

Note: **Anterior/posterior etching on the rails ensures proper loading of lordotic implants.**



While holding the implant against the pusher, turn the T-handle clockwise until the implant is engaged by both rails. Maintain compression on the rails to retain the implant.

Note: **Ensure that the implant is centered and follows the rails between the implant teeth.**

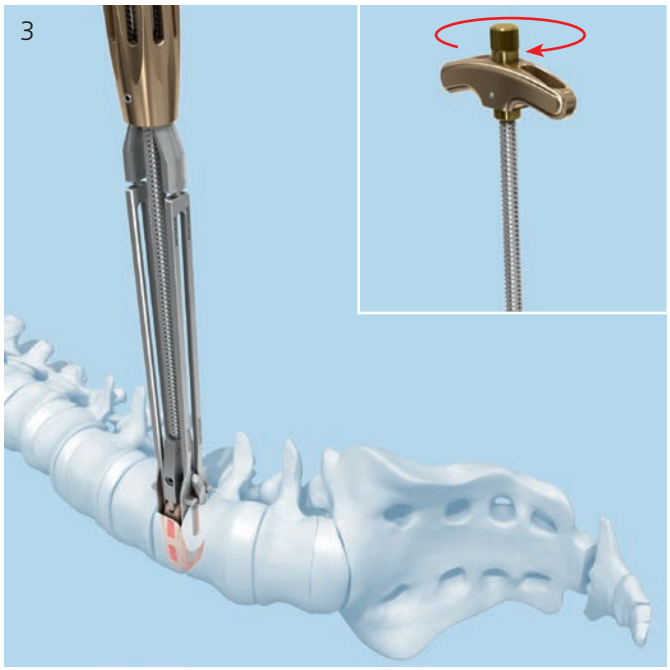


While maintaining compression on the rails, place the tips of the instrument into the disc space so the depth stops touch the lateral rim of the vertebral bodies. To ensure proper insertion of the implant, take an anterior/posterior fluoroscopic image to determine that the inserter is perpendicularly oriented in the intervertebral space and that the depth stops are touching the lateral rim of the vertebral bodies. The tips of the instrument are 35 mm in depth from the depth stops, 20 mm in width, and 1 mm thick.

While applying a firm and stationary force on the grip with one hand, turn the T-handle clockwise to advance the implant down the rails into the disc space (3). Using fluoroscopic images, verify the implant's progression and the location of the depth stops on the vertebral bodies.

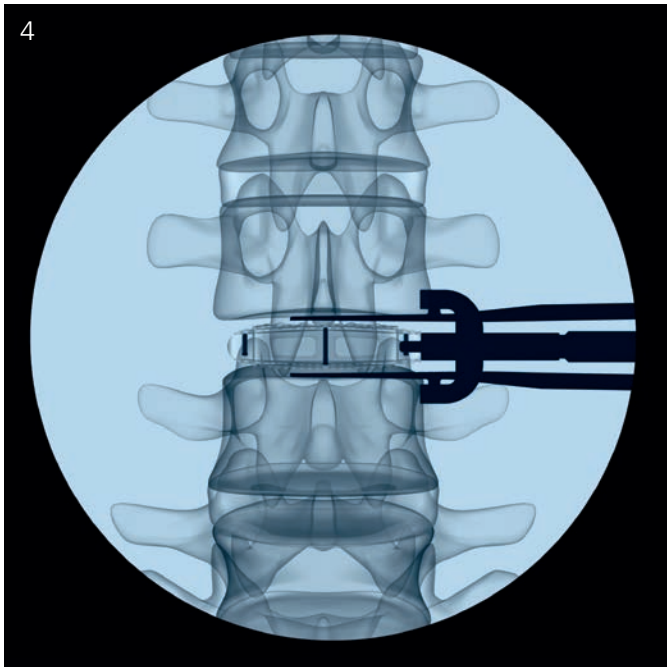
Continue turning the T-handle until it bottoms out on the grip. The inserter fully ejects and releases the implant.

Note: **Do not impact on the lateral quick inserter distractor. The instrument is designed to leave the implant 1 mm proud to the proximal aspect of the vertebral bodies. Depending on surgeon preference of final implant position, the surgeon may choose to use the Oracle impactor to seat the implant in its desired position (i.e. flush or recessed).**



Use fluoroscopy to determine the position of the implant. On an anterior/posterior fluoroscopic image, the two anterior/posterior radiopaque pins of the implant should appear as one marker. These pins should line up with the midportion of the spinous process or the lateral should be equidistant from the lateral edges of the vertebral bodies (4).

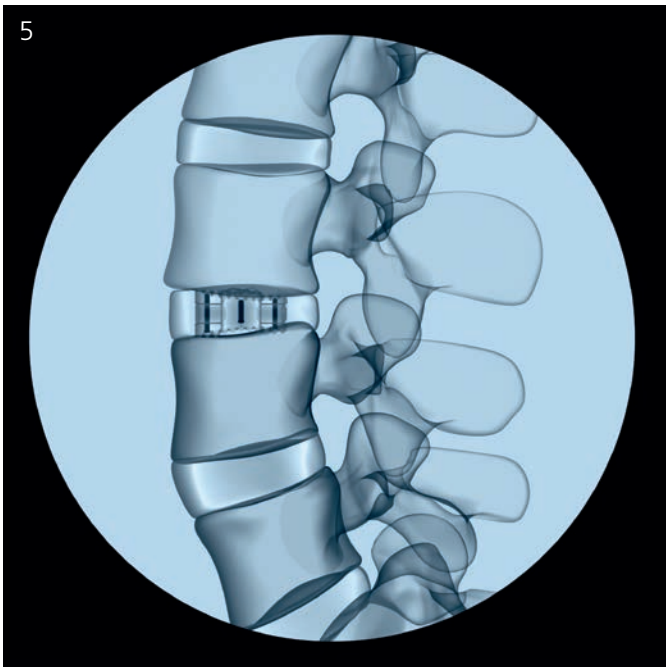
Note: **The medial/lateral marker pins of the implant are located approximately 4 mm from the edges of the implant.**



With a medial/lateral fluoroscopic image, the medial/lateral radiopaque pins of the implant should appear as one marker. The most anterior, middle radiopaque marker should be countersunk from the anterior edge of the vertebral bodies (5).

Note: **The anterior/posterior marker pins of the implant are located approximately 2 mm from the edges of the implant.**

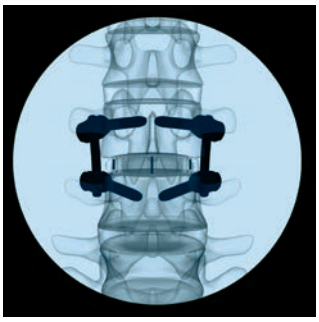
5



9
Supplemental Fixation

The Oracle Cage is intended to be used with supplemental fixation.

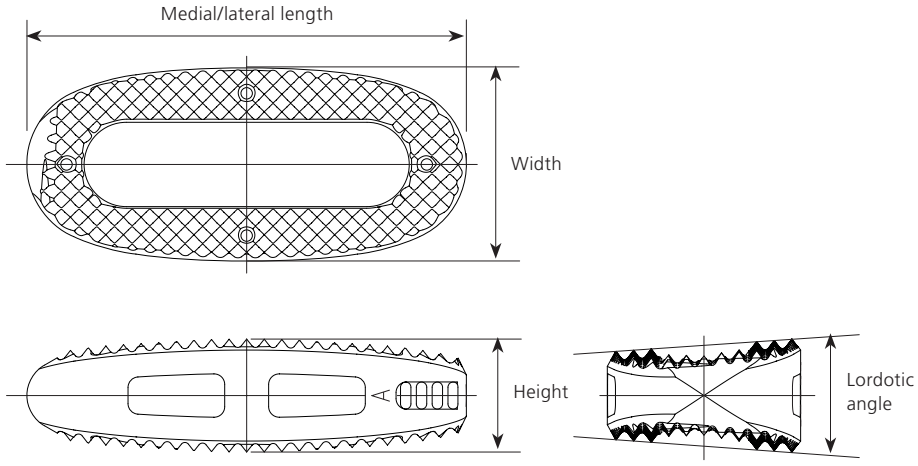
Lateral view of one-level Oracle cage and Pangea.



AP view of one-level Oracle cage and Pangea.

Graft volume

The table below shows the approximate graft volume that Oracle implants will hold, depending on the dimensions, heights and lordotic angulations. Please note that the width of all cages is 22 mm.

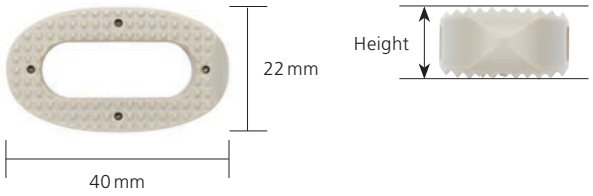


Filling volumes in cc

Lordotic angulation	0°					8°				
Medial/lateral length (mm)	Height (mm)									
	9	**11**	**13**	**15**	**17**	**9**	**11**	**13**	**15**	**17**
40	2.0	2.7	3.4	4.0	4.6	1.8	2.5	3.2	3.8	4.5
45	2.4	3.4	4.1	4.9	5.7	2.2	3.0	3.8	4.6	5.5
50	2.8	4.0	4.9	5.8	6.7	2.5	3.5	4.5	5.5	6.5
55	3.3	4.5	5.6	6.7	7.7	2.9	4.1	5.1	6.1	7.2

Oracle Cage, 0° angle, 40 mm × 22 mm

Art. no.	Height (mm)
08.809.209S	9
08.809.211S	11
08.809.213S	13
08.809.215S	15
08.809.217S	17

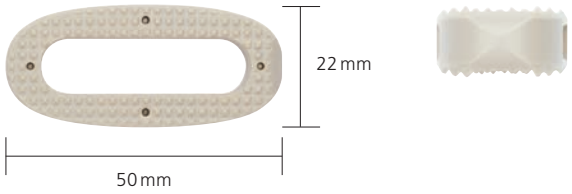


Oracle Cage, 0° angle, 45 mm × 22 mm

Art. no.	Height (mm)
08.809.229S	9
08.809.231S	11
08.809.233S	13
08.809.235S	15
08.809.237S	17

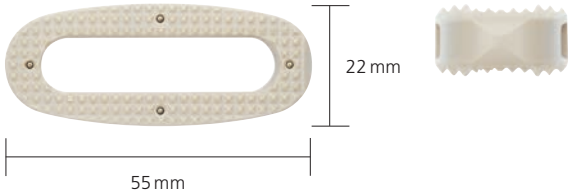
Oracle Cage, 0° angle, 50 mm × 22 mm

Art. no.	Height (mm)
08.809.249S	9
08.809.251S	11
08.809.253S	13
08.809.255S	15
08.809.257S	17



Oracle Cage, 0° angle, 55 mm × 22 mm

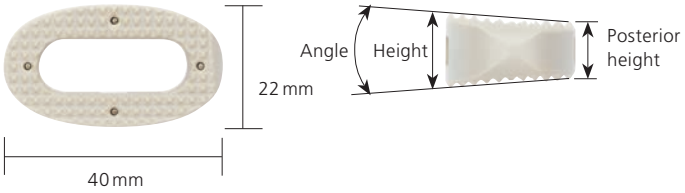
Art. no.	Height (mm)
08.809.269S	9
08.809.271S	11
08.809.273S	13
08.809.275S	15
08.809.277S	17



Note: Total combined height of teeth is 2 mm.

Oracle Cage, 8° angle, 40 mm × 22 mm

Art. no.	Height (mm)	Posterior height (mm)
08.809.609S	9	6
08.809.611S	11	8
08.809.613S	13	10
08.809.615S	15	12
08.809.617S	17	14

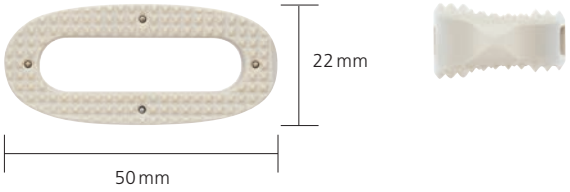


Oracle Cage, 8° angle, 45 mm × 22 mm

Art. no.	Height (mm)	Posterior height (mm)
08.809.629S	9	6
08.809.631S	11	8
08.809.633S	13	10
08.809.635S	15	12
08.809.637S	17	14

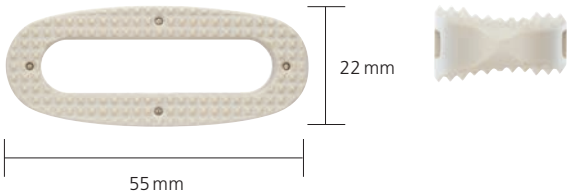
Oracle Cage, 8° angle, 50 mm × 22 mm

Art. no.	Height (mm)	Posterior height (mm)
08.809.649S	9	6
08.809.651S	11	8
08.809.653S	13	10
08.809.655S	15	12
08.809.657S	17	14



Oracle Cage, 8° angle, 55 mm × 22 mm

Art. no.	Height (mm)	Posterior height (mm)
08.809.669S	9	6
08.809.671S	11	8
08.809.673S	13	10
08.809.675S	15	12
08.809.677S	17	14



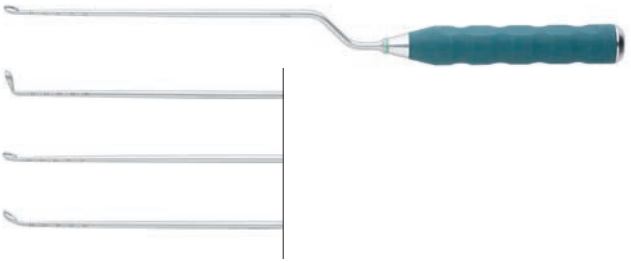
Note: Total combined height of teeth is 2 mm.

INSTRUMENTS

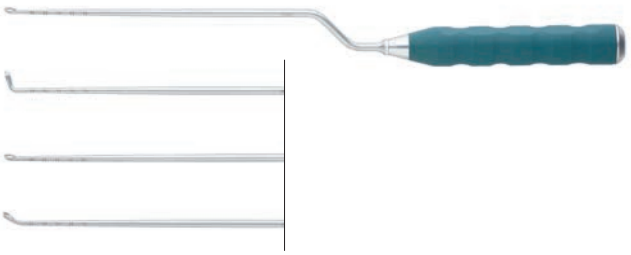
03.605.001	Rongeur for Intervertebral Discs, straight, width 4 mm, length 330 mm	
03.605.002	Rongeur for Intervertebral Discs, straight, width 6 mm, length 330 mm	
03.605.004	Periosteal Elevator, width 20 mm	
03.612.031	Fibre Optic Cable for Light Strip	
03.809.229– 03.809.237	Oracle Trial Implants, 0°, heights 9 mm–17 mm (2 mm increments)	
03.809.629– 03.809.637	Oracle Trial Implants, 8°, heights 9 mm–17 mm (2 mm increments)	
03.809.819– 03.809.827	Oracle Shavers, paddle-shaped, heights 9 mm–17 mm (2 mm increments)	

03.809.829– 03.809.837	Oracle Shavers, height 9 mm–17 mm (2 mm increments)	
03.809.849	Oracle Rasp	
03.809.857	Screwdriver Retractor Blade	

Oracle Curettes, bayoneted, width 7.5 mm

03.809.861	straight, up biting	
03.809.862	angled, forward biting	
03.809.863	straight, down biting	
03.809.864	angled, up biting	

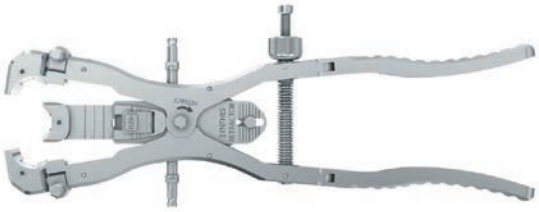
Oracle Curettes, bayoneted, width 5.5 mm

03.809.865	straight, up biting	
03.809.866	angled, forward biting	
03.809.867	straight, down biting	
03.809.868	angled, up biting	

03.809.869	Oracle Curette, bayoneted, 90° angled, up biting, width 7.5 mm	
03.809.870	Oracle Curette, bayoneted, 90° angled, up biting, width 5.5 mm	
03.809.872	Oracle Ring Curette, bayoneted, width of tip 8 mm	
03.809.873	Oracle Ring Curette, bayoneted, width of tip 6 mm	
03.809.874	Implant Holder for Oracle Cage	

Oracle Spreaders

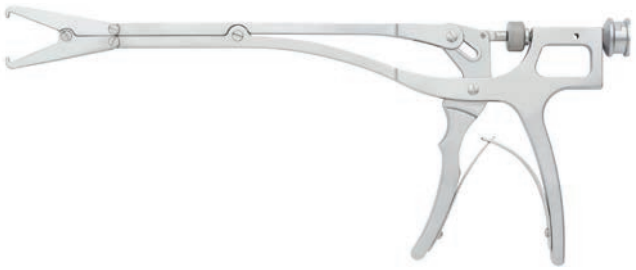
03.809.875	9 mm height	
03.809.876	11 mm height	
03.809.877	13 mm height	

03.809.881	Oracle Impactor	
03.809.900	Oracle Retractor Handle	
03.809.903– 03.809.915	Oracle Retractor Blades, 40 mm–160 mm, (10 mm increments) for No. 03.809.900	
03.809.918	Oracle Retractor Blade Extension	
03.809.919	Oracle Retractor Intradiscal Anchor	
03.809.921	Oracle Lateral Quick Inserter Distractor	

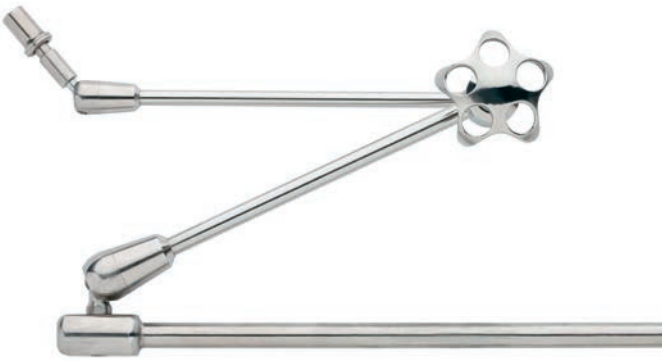
03.809.923 Retractor Extension Driver

03.809.930 Handle with Quick Coupling

03.809.940 Oracle Implant Remover



03.809.941 Universal Arm

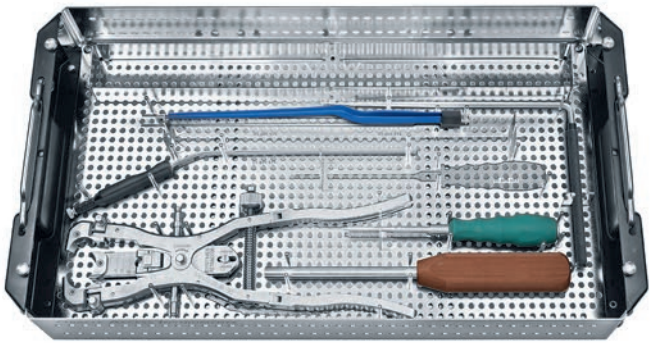


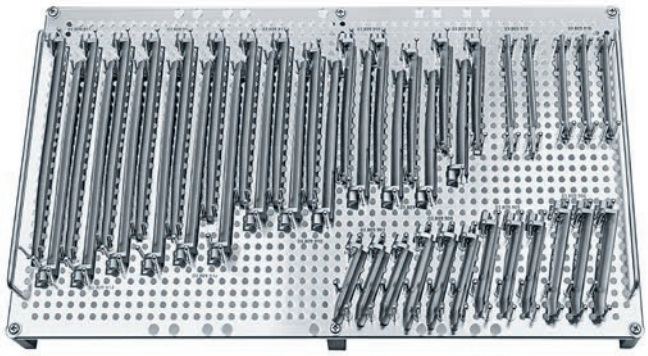
03.809.942 Table Clamp for Universal Arm

03.809.972	Oracle Slide Hammer	
03.809.973	Handle for Scalpel, long	
03.809.975	Long Suction Instrument	
03.809.977	Soft Tissue Retractor	

03.820.101	Screwdriver	
388.140	Socket Wrench 6.0 mm, with straight handle	
394.951	T-Handle with Quick Coupling	
SFW691R	Prodisc-L Combined Hammer	
03.605.010	Ball Tip Probe, length 300 mm	
03.809.860	Tissue Dissector	
03.605.012	Dissector, blunt, length 265 mm	
03.809.943	Retractor Pin, 3 ea.	

Oracle Access Instrument Set (01.809.002)





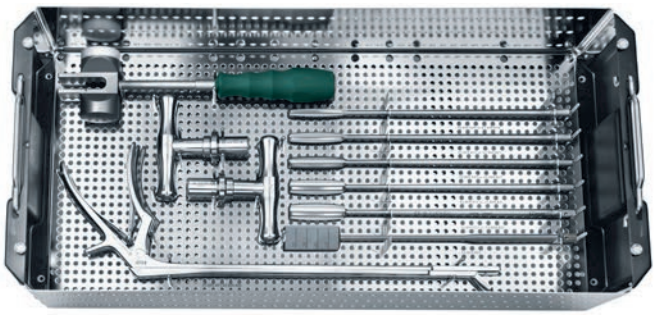
Vario Case	
68.809.002	Vario Case for Oracle Access Instruments, with Lid, without Contents

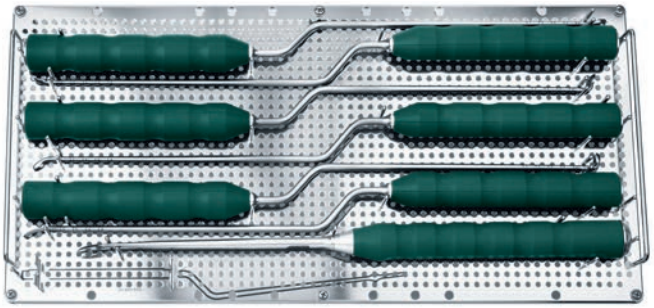
Instruments	
03.809.857	Retractor Blade Screwdriver
03.809.900	Oracle Retractor Handle
03.809.909	Oracle Retractor Blade, 100 mm, for No.03.809.900, 3 ea.
03.809.911	Oracle Retractor Blade, 120 mm, for No.03.809.900, 3 ea.
03.809.913	Oracle Retractor Blade, 140 mm, for No.03.809.900, 3 ea.
03.809.915	Oracle Retractor Blade, 160 mm, for No.03.809.900, 3 ea.
03.809.918	Oracle Retractor Blade Extension, 3 ea.
03.809.919	Oracle Retractor Intradiscal Anchor, 2 ea.
03.809.923	Retractor Extension Driver
388.140	Socket Wrench 6.0 mm, with straight handle

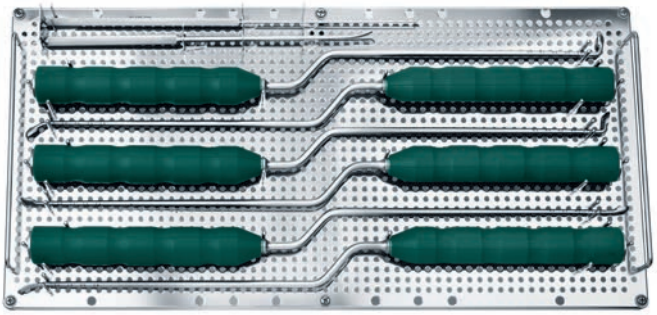
Optional

03.809.903	Oracle Retractor Blade, 40 mm, for No.03.809.900, 3 ea.
03.809.904	Oracle Retractor Blade, 50 mm, for No.03.809.900, 3 ea.
03.809.905	Oracle Retractor Blade, 60 mm, for No.03.809.900, 3 ea.
03.809.906	Oracle Retractor Blade, 70 mm, for No.03.809.900, 3 ea.
03.809.907	Oracle Retractor Blade, 80 mm, for No.03.809.900, 3 ea.
03.809.908	Oracle Retractor Blade, 90 mm, for No.03.809.900, 3 ea.
03.809.910	Oracle Retractor Blade, 110 mm, for No.03.809.900, 3 ea.
03.809.912	Oracle Retractor Blade, 130 mm, for No.03.809.900, 3 ea.
03.809.914	Oracle Retractor Blade, 150 mm, for No.03.809.900, 3 ea.
03.809.975	Long Suction Instrument
03.809.977	Soft Tissue Retractor
03.820.101	Screwdriver
03.809.860	Tissue Dissector
03.809.943	Retractor Pin, 3 ea.

Oracle Discectomy Instrument Set (01.809.003)







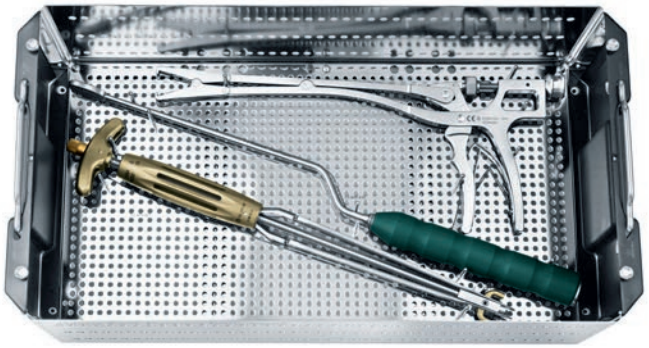
Vario Case	
68.809.003	Vario Case for Oracle Discectomy Instruments, with Lid, without Contents

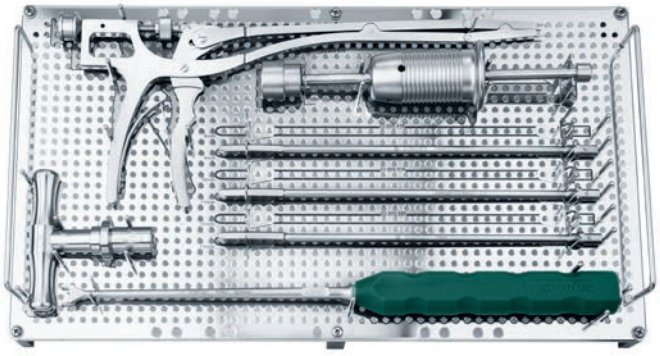
Instruments	
03.605.001	Rongeur for Intervertebral Discs, straight, width 4 mm, length 330 mm
03.605.002	Rongeur for Intervertebral Discs, straight, width 6 mm, length 330 mm
03.605.004	Periosteal Elevator, width 20 mm
03.605.010	Ball Tip Probe, length 300 mm
03.605.012	Dissector, blunt, length 265 mm
03.809.861	Oracle Curette, bayoneted, straight, up biting, width 7.5 mm
03.809.862	Oracle Curette, bayoneted, angled, forward biting, width 7.5 mm
03.809.863	Oracle Curette, bayoneted, straight, down biting, width 7.5 mm
03.809.864	Oracle Curette, bayoneted, angled, up biting, width 7.5 mm
03.809.865	Oracle Curette, bayoneted, straight, up biting, width 5.5 mm

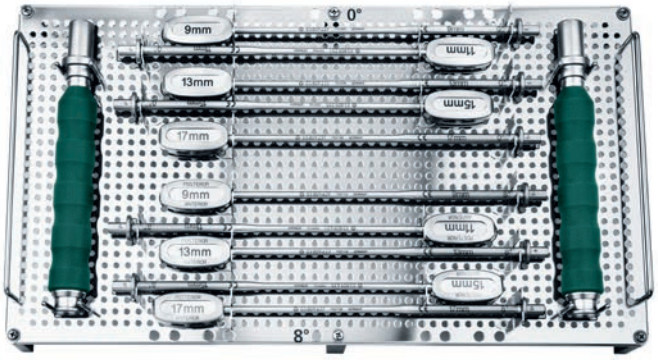
03.809.866	Oracle Curette, bayoneted, angled, forward biting, width 5.5 mm
03.809.867	Oracle Curette, bayoneted, straight, down biting, width 5.5 mm
03.809.868	Oracle Curette, bayoneted, angled, up biting, width 5.5 mm
03.809.869	Oracle Curette, bayoneted, 90° angled, up biting, width 7.5 mm
03.809.870	Oracle Curette, bayoneted, 90° angled, up biting, width 5.5 mm
03.809.872	Oracle Ring Curette, bayoneted, width of tip 8 mm
03.809.873	Oracle Ring Curette, bayoneted, width of tip 6 mm
SFW691R	Prodisc-L Combined Hammer

Optional	
03.809.819	Oracle Shaver, 9 mm, paddle-shaped
03.809.821	Oracle Shaver, 11 mm, paddle-shaped
03.809.823	Oracle Shaver, 13 mm, paddle-shaped
03.809.825	Oracle Shaver, 15 mm, paddle-shaped
03.809.827	Oracle Shaver, 17 mm, paddle-shaped
03.809.829	Oracle Shaver, 9 mm
03.809.831	Oracle Shaver, 11 mm
03.809.833	Oracle Shaver, 13 mm
03.809.835	Oracle Shaver, 15 mm
03.809.837	Oracle Shaver, 17 mm
03.809.973	Handle for Scalpel, long
394.951	T-Handle with Quick Coupling, 2 ea.

Oracle Cage Insertion Set (01.809.004)







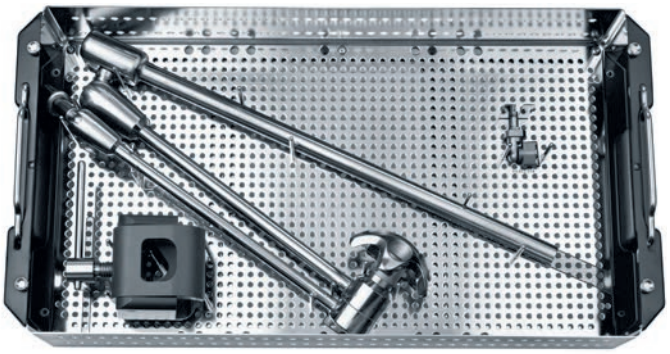
Vario Case	
68.809.004	Vario Case for Oracle Cage Insertion Instruments, with Lid, without Contents

Instruments	
Oracle Trial Implants, 0°	
03.809.229	height 9 mm
03.809.231	height 11 mm
03.809.233	height 13 mm
03.809.235	height 15 mm
03.809.237	height 17 mm
Oracle Trial Implants, 8°	
03.809.629	height 9 mm
03.809.631	height 11 mm
03.809.633	height 13 mm
03.809.635	height 15 mm
03.809.637	height 17 mm
03.809.849	Oracle Rasp
03.809.874	Implant Holder for Oracle Cage

Oracle Spreaders	
03.809.875	height 9 mm
03.809.876	height 11 mm
03.809.877	height 13 mm
03.809.881	Oracle Impactor
03.809.972	Oracle Slide Hammer
03.809.930	Handle with Quick Coupling, 1 ea.
03.809.940	Oracle Implant Remover
394.951	T-Handle with Quick Coupling

Optional	
03.809.921	Oracle Lateral Quick Inserter Distractor
03.809.930	Handle with Quick Coupling, 1 ea.

Stability System Set (01.809.018)



Vario Case	
68.809.006	Vario Case for Stability System, with Lid, without Contents

Instruments	
03.612.031	Fibre Optic Cable for Light Strip
03.612.014	Adapter for Three-blade Retractors, for No. 03.612.010
03.809.941	Universal Arm
03.809.942	Table Clamp for Universal Arm

ADDITIONAL SETS

Note: **The following are also optionally available for use with the Oracle Cage System**

Sets	
01.612.100	Set for MIS Support System
01.605.903	Set for Minimally Invasive Posterior Instruments
01.600.100	Proprep Set
01.809.011	Dilation Instrument Set
01.809.040	INSIGHT Lateral Access System Set

Instrument	
03.662.027S	Neuromonitoring Stimulation Probe
03.662.028S	Electrode Kit for Neuromonitoring
03.662.029	Handle for Neuromonitoring Stimulation Probe

Accessories	
03.809.925S	Light Clip for Oracle Retractor, sterile

FILLING MATERIAL

Synthetic cancellous bone graft substitute: chronOS
chronOS is a fully synthetic and resorbable bone graft substitute consisting of pure ß-tricalcium phosphate. Its compressive strength is similar to that of cancellous bone. Based on literature, the use of ß-tricalcium phosphate in the spinal column is a valuable alternative to allografts and autografts, even when larger amounts are required.[1]

Resorbable
It is remodeled to vital bone within 6–18 months

Osteoconductive
Interconnecting macropores of defined size (100–500 µm) facilitate bone ingrowth. Interconnected micropores (10–40 µm) allow an optimal supply of nutrients. The patient's blood, blood platelet concentrate or bone marrow aspirate enhances the properties of chronOS required for fusion.[2]

Safe
100% synthetic – no risk of cross infection

chronOS Granules

Art. no.	∅ (mm)	cc
710.000S	0.5–0.7	0.5
710.001S	0.7–1.4	0.5
710.002S	0.7–1.4	1
710.003S	0.7–1.4	2.5
710.011S	1.4–2.8	2.5
710.014S	1.4–2.8	5
710.019S	1.4–2.8	10
710.021S	1.4–2.8	20
710.024S	2.8–5.6	2.5
710.025S	2.8–5.6	5
710.026S	2.8–5.6	10
710.027S	2.8–5.6	20

[1] Muschik et al. 2001; Knop et al. 2006; Arlet et al. 2006
[2] Allman et al. 2002; Stoll et al. 2004; Becker et al. 2006

BIBLIOGRAPHY

Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols.), Stuttgart, New York: Thieme

Allmann M, Florias E, Stoll T, Hoerger F, Bart F (2002): Haematological evaluation of blood samples after vacuum like impregnation of a Beta-TCP ceramic bone substitute before implantation (internal communication)

Arlet V, Jiang L, Steffen T, Ouellet, J, Reindl R, Max Aebi (2006): Harvesting local cylinder autograft from adjacent vertebral body for anterior lumbar interbody fusion: surgical technique, operative feasibility and preliminary clinical results. Eur Spine J. 15: 1352–9

Becker et al. (2006) Osteopromotion by a ß-TCP/Bone Marrow Hybrid Implant for Use in Spine Surgery. Spine, Volume 31(1): 11–17

Knop C, Sitte I, Canto F, Reinhold M, Blauth M (2006): Successful posterior interlaminar fusion at the thoracic spine by sole use of ß-tricalcium phosphate. Arch Orthop Trauma Surg, 126: 204–210

Müller ME, Allgöwer M, Schneider R, and Willenegger H: AO Manual of Internal Fixation, 3rd Edition. Berlin; Springer-Verlag 1991

Muschik M, Ludwig R, Halbhubner S, Bursche K, Stoll T(2001) Beta-tricalcium phosphate as a bone substitute for dorsal spinal fusion in adolescent idiopathic scoliosis: preliminary results of a prospective clinical study. Eur Spine J. 10 Suppl 2: 178–84

Perry O: "Fracture of the Vertebral Endplate in the Lumbar Spine." Acta Orthop. Scand. 1957; 25 (suppl.)

Stoll et al. (2004) New Aspects in Osteoinduction. Mat.-wiss. u. Werkstofftech, 35 (4): 198–202

Takatomo Moro, MD, Shin-ichi Kikuchi, MD, PhD, Shin-ichi Konno, MD, PhD and Hiroyuki Yaginuma, MD, PhD: 'An Anatomic Study of the Lumbar Plexus with Respect to Retroperitoneal Endoscopic Surgery.', Spine 2003; Volume 28, Number 5, pp 423-428

White AA and Panjabi MM: Clinical Biomechanics of Spine. Philadelphia. Lippincott, William and Wilkins. 1990. 7, 9

DePuy Synthes
COMPANIES OF Johnson&Johnson
People inspired™

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11
Fax: +41 61 965 66 00
www.depuysynthes.com

This publication is not intended for distribution in the USA.

Not all products are currently available in all markets.

All surgical techniques are available as PDF files at
www.depuysynthes.com/ifu

CE
0123

 036.000.266 DSEM/SPN/0814/0172(2) 10/15